

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV457868735US

Express Mail Label Number

July 9, 2004  
Date of DepositForm PTO-1390-MOD  
(REV 10-96)

U. S. Department of Commerce Patent and Trademark Office

ATTORNEY'S DOCKET NUMBER

TX/4-32304A

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/501210

INTERNATIONAL APPLICATION NO.  
PCT/EP03/00153INTERNATIONAL FILING DATE  
9 January 2003 (09.01.03)PRIORITY DATE CLAIMED  
10 January 2002 (10.01.02)TITLE OF INVENTION  
DRUG DELIVERY SYSTEMS FOR THE PREVENTION AND TREATMENT OF VASCULAR DISEASES COMPRISING  
RAPAMYCIN AND DERIVATIVES THEREOFAPPLICANT(S) FOR DO/EO/US  
PRESCOTT ET AL.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 16. below concern document(s) or information included.**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information: Application Data Sheet

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

107501210

INTERNATIONAL APPLICATION NO.  
PCT/EP03/00153ATTORNEY'S DOCKET NUMBER  
TX/4-32304A17. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492(a) (1)-(5)):**

Search Report has been prepared by the EPO or JPO ..... \$920

International preliminary examination fee paid to USPTO (37 CFR 1.482)  
..... \$730

No international preliminary examination fee paid to USPTO (37 CFR 1.482)  
but international search fee paid to USPTO (37 CFR 1.445(a)(2)). ..... \$770

Neither international preliminary examination fee (37 CFR 1.482) nor  
international search fee (37 CFR 1.445(a)(2)) paid to USPTO. .... \$1,080

International preliminary examination fee paid to USPTO (37 CFR 1.482)  
and all claims satisfied provisions of PCT Article 33(2)-(4). .... \$100

**CALCULATIONS PTO USE ONLY****ENTER APPROPRIATE BASIC FEE AMOUNT =**

\$ 920

Surcharge of \$130 for furnishing the oath of declaration later than ☐ 20 ☐ 30  
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	11	- 20 =	0	X \$ 18
Independent claims	9	- 3 =	6	X \$ 86
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$ 290

\$ 516

\$

**TOTAL OF ABOVE CALCULATIONS =**

\$ 1,436

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be  
filed (Note 37 CFR 1.9, 1.27, 1.28).

\$

**SUBTOTAL =**

\$ 1,436

Processing fee of \$130 for furnishing the English translation later than ☐ 20 ☐ 30 months from  
the earliest claimed priority date (37 CFR 1.492(f)).

\$

**TOTAL NATIONAL FEE =**

\$ 1,436

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied  
by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property

\$

**TOTAL FEES ENCLOSED =**

\$ 1,436

Amount to be:	\$
refunded	
charged	\$

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$1,436 to cover the above fees. A duplicate copy of this form is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Send all correspondence to the address associated with  
Customer No. 001095, which is currently:

Thomas Hoxie  
Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 430  
East Hanover, NJ 07936-1080

*Thomas R. Savitsky*  
Thomas R. Savitsky  
Attorney for Applicants  
Reg. No. 31,661  
(862) 778-7909